

REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

As stated in the Office Action Summary, claims 1-5, 9, 11-15, 19, 21, 30, 31, 34, 36 and 55-69 are pending. Applicants note with appreciation that claims -5, 9, 11-15, 19, 21, 30, 31, 34, and 36 are allowed. Claims 55-57 and 67-69 are cancelled herein without prejudice or disclaimer thereto. Applicants reserve the right to file at least one continuation application directed to any subject matter cancelled by way of the present amendment.

Rejections Under 35 U.S.C. §§102 and 103

Claims 55-57 and 67-69 stand rejected under 35 U.S.C. §102(b) as purportedly anticipated by Burke (U.S. Patent No. 5,215,991) ("Burke"). Claims 55-57 and 67-69 are cancelled herein without prejudice or disclaimer thereto. Thus, this rejection is moot.

Claims 55-69 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lipton (U.S. Patent No. 5,506,231), in view of Benos et al. and Burke (U.S. Patent No. 5,215,991). The present rejection is addressed with regard to claims 58-66.

Applicants traverse. In order to establish a case of *prima facie* obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art references must teach or suggest all of the claim limitations. See M.P.E.P. 2142. Applicants respectfully submit that these criteria have not been met in the present Office Action. The cited references, alone or in combination, fail to recite all of the elements of the presently claimed invention or to provide an expectation of success or motivation to arrive at the claimed invention.

Independent claim 58 recites a method of reducing, retarding or otherwise inhibiting the functional activity of HIV, when the HIV has infected a mammalian host cell. The method comprises administering to the mammal an effective amount of

HMA or DMA for a time and under conditions sufficient to reduce, retard or otherwise inhibit the functional activity of HIV in said host cell. Independent claim 64 recites a method for the treatment and/or prophylaxis of HIV infection or AIDS in a mammal, comprising administering to said mammal an effective amount of HMA or DMA.

The Office asserts that the primary reference, Lipton, discloses a method for treating patients infected with HIV, with calcium ion channel antagonists, including amiloride. Applicants submit that the claims are not obvious over the cited references, as would not be obvious to the skilled artisan that HMA and DMA could be used to treat AIDS.

Applicants note that neither HMA, DMA, nor even amiloride are exemplified in Lipton. The other references as combined with Lipton, Benos and Burke, do not address this deficiency, as it cannot be assumed that these compounds will all have similar effects. Benos discloses that adding either killed HIV virus, or purified gp120, to media bathing rat astrocytes results in changes in activity of a number of plasma-membrane-located ion channels and transporters, but does not teach or suggest the use of amiloride to inhibit the Vpu ion channel of HIV or treatment. The Office appears to argue that Benos discloses that amiloride negates the effect of HIV toxic protein to the cells. However, Benos merely discloses that HIV virions have the ability to alter amiloride-dependent ion transport pathways. Burke discloses amiloride, HMA and DMA as preferred by Na^+/H^+ exchange inhibitors. However, Burke fails to disclose or suggest the treatment HIV, or that HMA or DMA block Vpu ion channels of HIV or inhibit functional activity of HIV.

Therefore, neither Burke nor Benos disclose that HMA or DMA are useful in treating an HIV infected patient. The present claims are directed to the use of HMA/DMA against HIV. This is not taught by the combination of the three cited references.

Further, studies performed by Applicants have shown that HMA and DMA are effective Vpu ion channel blockers, while amiloride is not. Applicants have shown that the amiloride-sensitive NMDA receptor-channel complex, referred to in Lipton, is in fact insensitive to HMA. Thus, the statement in Burke that "amiloride and its analogues as herein recited are known to be similarly useful" is not applicable here,

as amiloride does not have the same effect as DMA and HMA as used in the presently claimed invention.

Applicants also note that AIDS related dementia is one of many symptoms of HIV infection, and only occurs in a small proportion of AIDS-affected individuals. To this end, the disclosure of dementia does not indicate that the same effects may be had on HIV and its symptoms in general. Thus, Lipton combined with Burke and Benos, does not recite each element of the present invention or provide an expectation of success.

Claims 55-57 and 67-69 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cragoe Jr., et al. (U.S. Patent No. 4,085,211) ("Cragoe"), in view of Burke (U.S. 5,215,991). The present rejection is addressed with regard to claims 58-66.

Cragoe fails to recite or suggest the reducing, retarding or otherwise inhibiting the functional activity of HIV, or the treatment/prophylaxis of HIV infection. Burke does not remedy this deficiency. As previously noted, Burke discloses amiloride, HMA and DMA as preferred by Na⁺/H⁺ exchange inhibitors. However, Burke fails to disclose or suggest the treatment HIV, or that HMA or DMA block Vpu ion channels of HIV or inhibit functional activity of HIV. The present claims are methods claims directed reducing, retarding or inhibiting the activity of the HIV virus, or treatment/prevention of HIV infection. These claimed methods are not disclosed or suggested by the cited references taken in combination and thus the references further fail to provide an expectation of success.

In light of the above, Applicants request that the rejections under 35 U.S.C. §§ 102 and 103 be withdrawn.

CONCLUSION

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this Amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (703) 836-6620 so that prosecution of the application may be expedited.

Respectfully submitted,

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(INCLUDING THE ATTORNEYS FROM BURNS DOANE SWECKER & MATHIS)

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